August 22, 2024 | Pages - 20+40 Spl Supplement | ₹60

R.N.I. No. MAHENG/2000/05366

CHRONICLE PHARMABIZ

A Saffron Media Publication ◆ Mumbai ◆ Vol.24 No.39

Thursday ◆ August 22, 2024 ◆ ₹60

IZ

.pharmabiz.com

pain relief combination odolac+paracetamol

tee under the chairmanship of Dr Lalit Kumar Gupta, director, Prof Department of Pharmacology, LCMH Hospital, New Delhi and one expert each from clinical pharmacology, orthopaedics and medicine. The sub-committee was recommended to co-opt subject experts as and when required.

In the DTAB meeting held on January 25, 2024, the DTAB said that the sub-committee was constituted through an office memorandum on December 15, 2022 and it evaluated the replies and clarifications presented by the firms, received through the CDSCO, in response to the notices issued in respect of the FDC.

Without elaborating the sub-committee findings, the Board concluded, "DTAB deliberated the matter and agreed for prohibiting the manufacture, sale and distribution for human use of FDC drug S(+) etodolac+ paracetamol."

As reported earlier, the Central govt prohibited the FDC etodolac+paracetamol, which was manufactured by various companies in the country, and Emcure's S(+) etodolac+paracetamol combination, through an order on September 7, 2018, with the reasons that the FDC may involve risk to human beings. The combination was one of the formulations which were prohibited based on the recommendation of a sub-committee under the Chairmanship of Dr Nilima Kshirsagar, which was formed to evaluate the 349 FDCs which were prohibited by the government in 2016 and 2017.

The sub-committee recommended 343 FDCs be prohibited, and of the remaining, three need to be restricted for specific indications and three others to be restricted to specific quantities/strengths of ingredients and for specific indications. ◆

Indian pharma industry all set to scale new peaks

Dr. Sanjay Agrawal

The Indian pharmaceutical industry is a key player in the global market, known for its robust capabilities in drug manufacturing and research and development (R&D). As the world's largest provider of generic medicines and a significant contributor to global vaccine production, India's pharma sector has witnessed substantial growth over the past few decades. This article explores the current state, challenges, opportunities, and future prospects of the Indian pharma industry.

Current state of Indian pharma industry

Market size and growth

The Indian pharmaceutical industry is valued at approximately $42 billion and is expected to grow to $65 billion by 2024 and further to $120 billion by 2030. India ranks third worldwide for pharmaceutical production by volume and 14th by value. The country accounts for 20 per cent of the global supply of generic medicines, making it a vital player in the global pharma market.

Key segments

- *Generic drugs:* India is the largest supplier of generic medicines globally, providing affordable alternatives to branded drugs. This segment dominates the Indian pharmaceutical market.
- *Over-the-Counter (OTC) medicines:* The demand for OTC medicines is rising due to increased consumer awareness and self-medication trends.
- *Active Pharmaceutical Ingredients (APIs):* India is a major producer of APIs, which are crucial for the production of various drugs.
- *Biosimilars:* With advancements in biotechnology, the production of biosimilars has seen significant growth, offering cost-effective alternatives to biologic drugs.
- *Vaccines:* India is a leading manufacturer of vaccines, supplying to more than 150 countries.

Key players

The Indian pharma industry is home to several prominent companies, including Sun Pharmaceuticals, Dr. Reddy's Laboratories, Cipla, Lupin, and Aurobindo Pharma. These companies have established a strong presence both domestically and internationally.

Drivers of growth

- **Cost efficiency**

India's cost-efficient production capabilities are a major driver of its pharmaceutical industry's growth. The lower cost of production in India is attributed to affordable labor, raw materials, and manufacturing facilities. This cost advantage enables Indian pharma companies to produce high-quality drugs at competitive prices.

- **Skilled workforce**

India boasts a large pool of skilled professionals in the pharmaceutical and biotechnological fields. The country's emphasis on science and technology education has produced a workforce proficient in R&D, manufacturing, and quality control.

- **Government support**

The Indian government has implemented several initiatives to support the pharmaceutical industry. The 'Pharma Vision 2020' aims to make India a global leader in end-to-end drug manufacturing. Policies such as the Production Linked Incentive (PLI) scheme encourage domestic production of APIs and key starting materials (KSMs), reducing dependency on imports.

- **Growing domestic market**

India's growing population, increasing healthcare awareness, and rising middle-class income levels contribute to the expanding domestic market for pharmaceuticals. The prevalence of chronic diseases and the aging population also drive the demand for healthcare products and services.

Challenges facing industry

- **Regulatory environment**

The regulatory environment in India can be complex and challenging. Stringent regulations, delays in drug approvals, and compliance issues can hinder the growth of the pharmaceutical industry. Ensuring consistent quality standards across all manufacturing units is another challenge that companies face.

- **Dependency on imports**

Despite its strong manufacturing capabilities, India is heavily dependent on imports for certain APIs and raw materials, primarily from China. This dependency poses a risk to the supply chain, as seen during the Covid-19 pandemic when disruptions in imports affected drug production.

- Intellectual Property Rights (IPR)

While India has made significant strides in strengthening its IPR framework, concerns remain about the protection of patents and the enforcement of IPR laws. Balancing the need for affordable medicines with the protection of intellectual property rights continues to be a challenge.

- **Price control**

The Indian government controls the prices of essential medicines through the National Pharmaceutical Pricing Authority (NPPA). While this ensures affordability, it can also impact the profitability of pharmaceutical companies, particularly those involved in the production of low-cost generics.

Opportunities for growth

- **Expanding R&D capabilities**

Investing in R&D is crucial for the Indian pharmaceutical industry to move up the value chain. Developing new drugs, biosimilars, and innovative drug delivery systems can open up new revenue streams. Collaboration with global pharmaceutical companies and research institutions can also enhance R&D capabilities.

- **Growth in biopharmaceuticals**

The biopharmaceutical segment offers significant growth opportunities. As the global demand for biologics and biosimilars increases, Indian companies can leverage their manufacturing prowess and cost advantages to capture a larger share of this market.

- **Digital transformation**

Adopting digital technologies such as artificial intelligence (AI), machine learning (ML), and blockchain can revolutionize the pharmaceutical industry. These technologies can streamline drug discovery, enhance supply chain management, and improve patient outcomes through personalized medicine.

- **Global expansion**

Expanding into new international markets can drive growth for Indian pharmaceutical companies. By establishing a presence in emerging markets in Africa, Latin America, and Southeast Asia, Indian companies can diversify their revenue streams and reduce dependency on traditional markets like the US and Europe.

- **Contract Research and Manufacturing Services (CRAMS)**

The CRAMS sector presents a significant opportunity for growth. Global pharmaceutical companies are increasingly outsourcing their research and manufacturing needs to cost-efficient destinations like India. By offering high-quality services at competitive prices, Indian companies can attract more international clients.

Future prospects

- **Policy reforms**

Continued policy reforms and government initiatives will play a crucial role in shaping the future of the Indian pharmaceutical industry. Simplifying regulatory processes, providing incentives for R&D, and promoting ease of doing business will enhance the industry's growth prospects.

- **Innovation and technology**

Innovation and technology adoption will be key drivers of future growth. Investing in advanced manufacturing technologies, personalized medicine, and telehealth can position Indian pharma companies at the forefront of global healthcare innovation.

- **Focus on quality**

Maintaining high-quality standards will be essential for the industry's success. Indian pharmaceutical companies must invest in quality control and assurance to meet global standards and build trust with international clients and regulators.

- **Addressing supply chain vulnerabilities**

Reducing dependency on imports for APIs and raw materials is crucial for the industry's resilience. Developing a robust domestic supply chain and investing in API manufacturing will mitigate risks and ensure a stable supply of essential drugs.

- **Public-private partnerships**

Collaboration between the government and private sector can drive innovation and growth. Public-private partnerships can facilitate the development of healthcare infrastructure, R&D capabilities, and skill development initiatives.

Role of startups and innovation

- **Startup ecosystem**

India's startup ecosystem is thriving, with numerous pharmaceutical and biotech startups emerging. These startups are driving innovation in drug discovery, healthcare delivery, and biotechnology.

CONTINUED ON p20▶

Indian pharma companies expanding global footprint

CONTINUED FROM p8

They are leveraging new technologies like AI and genomics to develop novel therapies and personalized medicine.

- **Venture capital and funding**

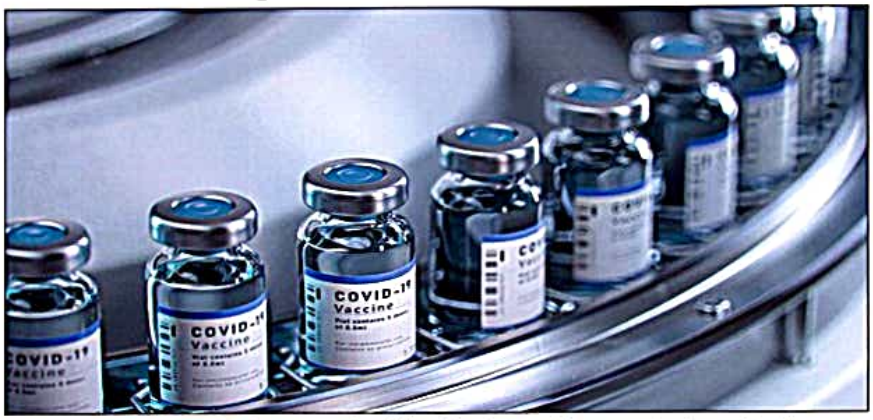
Increased venture capital investment in pharma and biotech startups is providing the necessary funding for research and innovation. Government grants and funding programs, such as the Biotechnology Industry Research Assistance Council (BIRAC), are also supporting startups in their early stages.

Impact of Covid-19

- **Accelerated vaccine development**

The Covid-19 pandemic showcased India's capability in rapid vaccine development and mass production. Indian companies like Serum Institute of India and Bharat Biotech played crucial roles in producing Covid-19 vaccines, reinforcing India's position as a global vaccine hub.

- **Enhanced focus on health security**



The pandemic has highlighted the importance of health security and the need for a robust pharmaceutical industry. This has led to increased investments in healthcare infrastructure, R&D, and domestic manufacturing capabilities.

Export potential

- Increasing global footprint

Indian pharmaceutical companies are expanding their global footprint by exporting to more than 200 countries. Efforts to comply with international regulatory standards and obtain certifications from agencies like the US FDA and EMA have opened new markets and boosted export potential.

- **Strategic partnerships**

Strategic partnerships with global pharmaceutical giants for co-development, licensing, and distribution are providing Indian companies access to advanced technologies and new markets. These collaborations are mutually beneficial, driving growth and innovation.

Talent development and education

- **Industry-academia collaboration**

Collaborations between the pharmaceutical industry and academic institutions are vital for talent development and innovation. Joint research programs, internships, and training initiatives are bridging the gap between academia and industry, ensuring a steady supply of skilled professionals.

- **Specialized training programs**

The introduction of specialized training programs in pharmaceutical sciences, biotechnology, and regulatory affairs is equipping the workforce with the necessary skills to meet industry demands. Continuous professional development and certification programs are also enhancing the capabilities of existing professionals.

Government initiatives and policy support

- **Atmanirbhar Bharat (Self-reliant India)**

The Atmanirbhar Bharat initiative aims to make India self-reliant in various sectors, including pharmaceuticals. Policies promoting domestic manufacturing of APIs and reducing dependency on imports are strengthening the industry's foundation.

- **Fostering innovation**

Government initiatives such as the Startup India program and the National Biopharma Mission are fostering innovation and entrepreneurship in the pharmaceutical sector. These initiatives provide funding, mentorship, and infrastructure support to startups and researchers.

Sustainable practices and environmental responsibility

- **Green chemistry**

The adoption of green chemistry principles is reducing the environmental impact of pharmaceutical manufacturing. Sustainable practices in drug synthesis, waste management, and energy consumption are becoming increasingly important.

- **Corporate Social Responsibility (CSR)**

Pharmaceutical companies are actively engaging in CSR activities, focusing on improving public health, supporting community healthcare initiatives, and enhancing access to medicines. These efforts are building a positive image and contributing to societal well-being.

Future trends and technologies

- **Precision medicine**

The rise of precision medicine, which tailors treatments based on individual genetic profiles, is set to revolutionize healthcare. Indian companies are investing in genomics and bioinformatics to develop personalized therapies.

- **Digital health**

The integration of digital health technologies, such as telemedicine, mobile health apps, and wearable devices, is transforming patient care. These technologies enable remote monitoring, real-time health data analysis, and improved patient outcomes.

- **Nanotechnology**

Nanotechnology is emerging as a promising field in drug delivery and diagnostics. Indian researchers and companies are exploring the use of nanomaterials to develop more effective and targeted therapies.

Conclusion

The Indian pharmaceutical industry is poised for a transformative future, driven by innovation, strategic investments, and robust government support. By addressing challenges, embracing new technologies, and fostering a culture of research and development, India can solidify its position as a global pharmaceutical leader. The industry's potential for growth and its ability to contribute significantly to global healthcare make it a crucial player in the world economy. With a forward-looking approach and collaborative efforts, the Indian pharma industry is set to achieve new heights in the coming years. ◆

(The author is leading pharmaceutical consultant and Editor- in Chief of IJMToday)